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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/565,933	01/20/2006	Sascha Kruger	DE 030264	9385
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EXAMINER HOFFA, ANGELA MARIE				
ART UNIT 4138		PAPER NUMBER		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/565,933

Applicant(s)

KRUGER ET AL.

Examiner

Angela M. Hoffa

Art Unit

4138

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 January 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/US)
- Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date ____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____.

DETAILED ACTION

1. This office action is in response to application No. 10565933 filed on January 20, 2006. This application is a 371 of PCT/IB04/51207 filed on July 13, 2004.

Priority

2. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Specification

3. Applicant is reminded of the proper format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

4. The abstract of the disclosure is objected to because it exceeds 150 words of length. Correction is required. See MPEP § 608.01(b).
5. The disclosure is objected to because of the following informality: Reference characters must have a consistent label. In the Abstract, character "20" is used to reference "control and measurement facilities" as well as a "particle-measuring unit". On Page 9, Line 16, character "20" is referencing an "analytical facility". Appropriate correction is required.

Claim Objections

6. Claims 1, 4, 5, 9 and 12 are objected to because of the following informalities:

In Claim 1, the figure label "10" is previously referencing an "optical unit" in the specification not a "cavitation unit" or "particle-measuring unit" as in the claim.

Regarding Claim 4, the figure label "3" is previously referencing "cavitation bubbles" in the specification and parent claim. In Claim 4, the figure label incorrectly refers to "particles".

In Claim 5, "receive light selectively from a focus region (2) situated outside the catheter and/or beam it into the focus region (2)" is a contradictory statement. It is interpreted as "receive light selectively from a focus region (2) which is situated outside the catheter and/or beam light selectively into a focus region (2) which is situated outside the catheter".

In Claim 9, "comprises in that it comprises" should read "characterized in that it comprises".

In Claim 12, the character "20" has previously been used to reference a "particle-measuring unit" but here is describing an "activation unit".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 4 recites the limitation "the light" in Line 2 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1-4 and 13 rejected under 35 U.S.C. 102(b) as being anticipated by Publication "Flow Rate Measurement using Ultrasonic Doppler Method with Cavitation Bubbles" to *Koike et al.*

In regards to Claim 1, *Koike et al* discloses a device for measuring flow in a fluid, comprising a cavitation unit ("cavitation bubbles generating system") and a particle-measuring unit ("measurement system"), (Page 2, Paragraph 2, Lines 1-6; Figure 2).

In regards to Claim 2, *Koike et al* discloses a cavitation unit that uses an ultrasonic source ("ultrasonic cavitation bubbles generating system", Figure 1).

In regards to Claim 3, *Koike et al* discloses a particle-measuring unit utilizing the Doppler shift ("Ultrasonic pulse Doppler Method", Abstract, Line 3).

In regards to Claim 4, *Koike et al* discloses a particle-measuring unit that detects reflected light from cavitation bubbles (Abstract, Lines 7-9). A unit that is capable of detecting light reflected by the bubbles is capable of detecting light emitted by the bubbles as there is no dependence on the source of the light.

In regards to Claim 13, *Koike et al* discloses a method of measuring fluid flow wherein cavitation bubbles are generated and the movement of the bubbles is observed (Abstract).

11. Claims 5-9, 11, and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent Publication No. 2002/0045811 A1 to *Kittrell et al*.

In regards to Claim 5, *Kittrell et al* discloses a facility comprising a catheter with an optical unit at its tip that receives or transmits light into a focused region wherein the radial position of the focus region can be adjusted externally (Abstract, Paragraph 0106, Lines 15-20; Paragraph 0093).

In regards to Claim 6, *Kittrell et al* further discloses an optical unit that can be rotated around the catheter axis relative to the catheter (Paragraph 0093, Lines 5-8).

In regards to Claim 7, *Kittrell et al* further discloses a catheter comprising a "coherent bundle" of optical waveguides (Paragraph 0088).

In regards to Claim 8, *Kittrell et al* further discloses a scanning unit that varies the position of the lasing region (Paragraph 0158, Lines 21-24) based on the analysis of light picked up from the focus region with regard to characteristic properties of the area (Paragraphs 0150; Figure 24).

In regards to Claim 9, *Kittrell et al* further discloses use of a spectrometer ("spectral analyzer 60", Paragraph 0117).

In regards to Claim 11, *Kittrell et al* further discloses an activation unit ("coupler 46", Paragraph 0068, Lines 1-4) used to inject light into a focus region

whereby initiating local processes such as removing lesions or obstructions in a vessel (Paragraph 0158, Lines 1-4).

In regards to Claim 14, *Kittrell et al* further discloses a method for determining the position of a vessel wall using qualitative spectroscopic characteristic changes (Paragraph 0128, Lines 9-10; Paragraph 0127). Methods for continuously displacing the focus region for the intended use of determining the position of a vessel wall are also disclosed (Paragraphs 0093 and 0102).

12. Claims 5 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Publication "Measurement of the Velocity of Blood Flow (in vivo) Using a Fiber Optic Catheter and Optical Mixing Spectroscopy" to *Tanaka et al*.

Regarding Claim 5, *Tanaka et al* discloses a facility with an optical unit that can transmit and receive light and radially position a region of focus (Figure 2; Page 192, Paragraph 3, Lines 24-28).

Regarding Claim 10, *Tanaka et al* further discloses a particle measuring unit that measures flow using the Doppler anemometry technique (Figure 2; Page 190, Paragraph 2).

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

15. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Publication 2002/0045811 A1 to *Kittrell et al* as applied to the claims above in view of U.S. Patent No. 5,116,227 to *Levy*.

Regarding Claim 12, *Kittrell et al* discloses a facility for a laser ablation process utilizing a focusing region (Abstract).

Kittrell et al does not expressly disclose the generation of cavitation bubbles by the lasing process in a focused region.

However, *Levy* teaches an optic laser tool that can be inserted in a passage where the laser is focuses in a specific region (Column 1, Lines 58-64). *Levy* further discloses the use of cavitation bubbles created by the optic laser tool in the focused region (Column 3, 31-35).

Kittrell et al and *Levy* are analogous art because they are from the same field of endeavor with respect to laser surgical tools.

At the time of invention, it would have been obvious to a person of ordinary skill in the art that cavitation bubbles can be created in a laser focused region. The

motivation/suggestion would have been to erode an area in the focused region (Column 3, 21-23).

Conclusion

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- U.S. Patent 6,428,531 B1 to *Visuri et al* discloses a removal of occlusions in blood vessels employing the use of cavitation bubbles.
- Publication "Velocity Measurements and Visualizations of the Flow Driven by Laser-Induced Cavitation Bubbles in a Blood-like Liquid" to *Molho et al* discloses the generation and detection of cavitation bubbles.
- U.S. Patent No. 4,662,749 to *Hatton et al* discloses a fiber optic probe capable of measuring light from bubbles to measure flow velocity.
- U.S. Patent Number 5,109,859 to *Jenkins* discloses a catheter system that employs ultrasound and optics for tissue ablation.
- U.S. Patent No. 6,166,806 to *Tjin* discloses a fiber optic catheter used for flow measurements.
- U.S. Patent Number 5,041,108 to *Fox et al* discloses a laser catheter with a scanning element that scans the cross-sectional area of a vessel.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Angela M. Hoffa whose telephone number is (571)270-7408. The examiner can normally be reached on Monday - Friday, 7:30 am - 5:00 pm with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Melba Bumgarner can be reached on 571-272-4709. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/A. M. H./
Examiner, Art Unit 4138

/Melba Bumgarner/
Supervisory Patent Examiner
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